

### REMARKS

The Office Action mailed November 17, 2004 has been carefully considered by applicant. Reconsideration is respectfully requested in view of the foregoing amendments to the claims and drawings, and the remarks that follow.

#### Formal Drawings

The Examiner requires formal drawings. Herewith applicant submits formal drawing figures 1-8, in accordance with the requirements in the Office Action. No new matter is added by this Amendment. The drawings are thus believed in condition for allowance.

#### Claim Objections

Claim 6 has been objected to for the use of an acronym. By the present amendment, claim 6 is amended to delete the acronym and insert the word "frontal electromyography".

Claims 12 and 19 have been objected to as containing a typographical error. By the present amendment, claims 12 and 19 are amended to correct the noted typographical error.

Claims 6, 12 and 19 are thus believed in condition for allowance.

#### Claim Rejections under 35 USC §112

Claim 2 has been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection under §112 is respectfully traversed.

Claim 2 depends from claim 1 and thus incorporates the subject matter thereof. Original claim 1 defined the step of "positioning a second electrode above the first electrode on the fronto-lateral area of the frontal lobe of the patient and on the same hemisphere as the first electrode". Claim 2 further defines the position of the second electrode as "positioned as far as possible from the first electrode". It is understood that this text therefore places the second electrode as far as possible from the first electrode on the frontal lateral area of the frontal lobe of the patient and on the same hemisphere

as the first electrode. This recitation is believed to be definite and satisfies the requirements of §112.

Similar reasoning applies to the claim language "the fourth electrode is positioned as far as possible from the third electrode", per claim 2. Claim 1 defines the step of "positioning a fourth electrode above the third electrode on the fronto-lateral area of the frontal lobe of the patient and on the same hemisphere as the third electrode." Claim 2 thus recites that the fourth electrode is positioned as far as possible from the third electrode on the frontal lateral area of the frontal lobe of the patient and on the same hemisphere as the third electrode. This recitation is thus believed definite and satisfies the requirements of §112.

#### Claim Rejections under 35 USC §102

Claims 1-10 and 18-24 have been rejected under 35 USC §102(b) as being anticipated by Imram U.S. Patent No. 5,479,934. Claims 11-17 have been rejected under 35 USC §102(b) as being anticipated by Brown U.S. Patent No. 6,032,065. By the present Amendment, independent claims 1, 11 and 18 are amended to more particularly point out and distinctly claim the subject matter of the invention and render the same allowable over the applied references.

In general, the present invention relates to a method of positioning electrodes in an electrode array comprising at least five or seven electrodes for monitoring the central nervous system of a patient using electroencephalography (EEG), frontal electromyography (FEMG) and eye movement (EM) signals from a patient's forehead. The invention provides a simple and practical method of positioning the electrode array so that electrodes of the array are optimally located for discriminating EEG, FEMG and EM components from recorded biopotential signals.

Various embodiments of the invention are claimed in independent claims 1, 11 and 18. The claims are hereby amended to more particularly recite that a first electrode is positioned "above the eye brows" and in a position where it can sense "a signal from the frontalis and at least one of the corrugator, procerus, and orbicularis muscles of the patient", and can be "optimized to detect phasic and tonic activation of facial muscles expressing painful mimic responses." The claims are also amended to

more particularly recite that the third electrode is positioned "above the eyebrows" and in a position such that it can sense "a signal from the frontalis and at least one of the corrugator, procerus, and orbicularis muscles of the patient" and can be "optimized to detect phasic and tonic activation of facial muscles expressing painful mimic responses." These steps (and positioning of the at least five electrodes) are not taught by the prior art, including the cited references.

To aid in the Examiner's understanding of the claimed invention, the attached web page includes an illustration of the various muscles recited in the claims. The palpebral and orbital portions of the orbicularis muscle are denoted by reference letters A and B, respectively. The frontalis muscle is shown at C, the procerus muscle is at D, and the corrugator muscle is at E.

The steps of claim 1 position the electrodes to allow for at least two of electroencephalography, frontal electromyography and eye movement signals to be distinguished from each other and a level of patient sedation to be assessed. The steps of claim 11 position the electrodes to allow for biopotential signals from both cordial hemispheres to be measured for functional comparison to detect non-symmetries between the hemispheres and eye movements can be detected. The steps of Claim 18 are a combination wherein the results described above for claims 1 and 11 are achieved.

Imran U.S. Patent No. 5,479,934 fails to teach or suggest the steps of the claims 1, 11 and 18 and fails to teach or suggest an arrangement that achieves the claimed results. For example, Imran '934 fails to teach or suggest that the first and third electrodes are positioned to sense a signal from the frontalis and at least one of the corrugator, procerus and orbicularis muscles of the patient. In contrast, the electrode 31 shown in Fig. 3 of Imran '934 is placed in the area "C" (frontalis muscle), shown in the attached web page. This is not surprising because Imran follows the International 10-20 system, which is discussed in the present application on page 1, lines 18-22 and page 2, lines 18-16. The present invention is distinguished from the 10-20 system throughout the application and in fact, the present invention is a clear advancement over the 10-20 system.

Referring to Brown '065, the electrode 28 is also not positioned above the eye brows near the frontal and orbicularis muscles of the patient, per the independent claims of the present application. This can be seen easily when comparing Figs. 1 and 2 of Brown '065 and the enclosed web page showing facial muscles for the human face. It is therefore impossible to use the teachings of Brown '065 to achieve the results of claims 1, 11 and 18, and as described on page 5, lines 23-30 of the present application.

Only according to the invention of claim 1 is an array of at least five electrodes positioned such that at least two of electroencephalography, frontal electromyography and eye movement signals are distinguishable from each other and a level of patient sedation is assessable. This is impossible using the teachings in Imran '934 and/or Brown '065. Similarly, only according to the invention of claim 11 is an array of at least five electrodes positioned such that biopotential signals from both cortical hemispheres can be measured for functional comparison to detect non-symmetries between the hemispheres and eye movements are detectable. Only according to claim 18 are the results of both claims 1 and 11 achieved. As such, claims 1, 11 and 18 of the present application are believed allowable over the applied references.

Claims 2-10 depend directly or indirectly from claim 1 and are believed allowable for the reasons stated above as well as the subject matter recited therein.

Claims 12-17 and 25 depend directly or indirectly from claim 11 and are thus believed allowable for the reasons stated above, as well as the subject matter recited therein.

Claims 19-24 and 26 depend directly or indirectly from claim 18 and are thus believed allowable for the reasons stated above, as well as the subject matter recited therein.

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Conclusion

The present application is thus believed in condition for allowance with claims 1-26. Such action is respectfully requested.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Peter T. Holsen", written over the printed name.

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**Amendments to the Drawings:**

The attached sheet of drawings include formal drawing Figs. 1 - 8.

Attachment: Replacement Sheets of 4 pages